10/594597

## IAPS Rec'd PCT/PTO 28 SEP 2006

Docket No.: 0649-1380PUS1 (PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Kazutaka IKEDA et al.

Application No.: NEW

Confirmation No.:

Filed: September 28, 2006

Art Unit: N/A

For:

METHOD OF EVALUATING DRUG

SENSITIVITY BY ANALYZING THE MU-

OPIOID RECEPTOR GENE

Examiner: Not Yet Assigned

## **INFORMATION DISCLOSURE STATEMENT (IDS)**

MS PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement accompanies the new patent application submitted herewith.

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

IAP5 Rec'd PCT/PTO 28 SEP 2006

10/594597

Application No.: NEW

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A concise explanation of relevance of the items listed on form PTO/SB/08 is in the form

of an English language copy of a Search Report from a foreign patent office, issued in a

counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement

shall not be construed to mean that a search has been made or that no other material information

as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this

Information Disclosure statement shall not be construed to be an admission that any patent,

publication or other information referred to therein is "prior art" for this invention unless

specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR

1.98 and the Examiner is respectfully requested to consider the listed references.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future

replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for

any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of

time fees.

Dated: September 28, 2006

Respectfully submitted,

Registration No.: 36,623

BIRCH, STEWART, MOLASCH & BIRCH, LLP

8110 Gatehouse Road

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant

2 DRN//sll

## IAP5 Rec'd PCT/PTO 28 SEP 2006

PTO/SB/08a/b (07-06)

Approved for use through 09/30/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				Complete if Known			
				Application Number	NEW 0/50/507		
	NFORMATION	l DI	SCLOSURE	Filing Date	September 28, 2006		
STATEMENT BY APPLICANT				First Named Inventor	Kazutaka IKEDA		
				Art Unit	N/A		
L	(Use as many sheets as necessary)			Examiner Name	Not Yet Assigned		
Sheet	1	of	1	Attorney Docket Number	0649-1380PUS1		

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or	Pages, Columns, Lines, Where	
		Number-Kind Code <sup>2</sup> ( if known)		Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		,				

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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	CA	Shi, J. et al., Sequence variations in the mu-opioid receptor gene (OPRM1) assocaited with human addiction ot heroin, Hum Mutat, 2002, Vol. 19, No. 4, pages 459 to 460.	ISR
	СВ	Szeto, C.Y. et al., Association between mu opioid receptor gene polymorphisms and Chinese heroin addicts, Neuroreport, 2001, Vol. 12, No. 6, pages 1103 to 1106.	ISR
	СС	Gelernter, J. et al., Genetics of two mu opioid receptor gene (OPRM1) exon I polymorphisms: population studies, and allele frequencies in alcohol - and drug-dependent subjects, Mol.Phychiatry, 1999, Vol. 4, No. 5, pages 476 to 483.	ISR
	CD	HIROTA, T. et al., Sequence variability and candidate gene analysis in two cancer patients with complex clinical outcomes during morphine therapy, Drug Metab.Dispos., 2003, Vol. 31, No. 5, pages 677 to 680.	ISR
	CE	Hoehe, M.R. et al., Sequence variability and candidate gene analysis in complex disease: association of mu opioid receptor gene variation with substance dependence, Hum.Mol.Genet., 2000, Vol. 9, No. 19, pages 2895 to 2908.	ISR
	CF	Uhl, G.R. et al., The mu opiate receptor as a candidate gene for pain: polymorphisms, variations in expression, nociception, and opiate responses, Proc.Natl.Acad.Sci.USA, 1999, Vol. 96, No. 14, pages 7752 to 7755.	ISR
	CG	Mayer, P. et al., Allelic and somatic variations in the endogenous opioid system of humans, Pharmacol.Ther., 2001, Vol 91, No. 3, pages 167 to 177.	ISR

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

GM

Examiner	Date	
Signature [	 Considered	

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.